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Remarks

The above-identified application has been carefully reviewed in light of the Examiner's office action mailed on August 16, 2006, which included a final rejection of all claims presented. Applicant hereby respectfully requests reconsideration of the Examiner's rejections in view of the following remarks.

Claims 30-33 and 36-45 continue to be rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over, Fox (U.S. Pat. No. 6,325,806). Claims 34 and 35 continue to be rejected under 35 U.S.C. 103(a) as being unpatentable over Fox as applied to claim 30 and further in view of Shiber (U.S. Pat. No. 4,885,458). Applicant traverses each of these rejections.

The present claims provide methods of removing material from a breast of a human or animal. The methods remove material from a breast less invasively and/or with reduced risk to the patient relative to many prior art devices and procedures.

Independent claim 30 is directed to a method of removing material from a breast which comprises the steps of placing into a breast of a human or an animal a cannula having an open, distal tip and a rotational element disposed at least partially in the cannula, and rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open, distal tip of the cannula.

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Fox discloses instrumentation for collecting bone cuttings.

Fox does not disclose, teach or suggest the present invention as claimed. Fox does not disclose, teach or even suggest any methods of removing material from a breast, let alone a method comprising placing into a breast a cannula having an open distal tip and a rotational element disposed at least partially in the cannula and rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open distal tip of the cannula, as recited in the present claims.

In view of the above, applicant submits that Fox does not anticipate the present claims, in particular claims 30-33 and 36-45, under 35 U.S.C. 102(e).

Moreover, Fox does not even suggest utilizing the instrument disclosed or the methodology taught to remove material from any body structure other than bone, let alone from a breast. Simply put, the method of cutting a bone disclosed by Fox provides no motivation or incentive to a person of ordinary skill in the art to use the Fox instrument and methodology for removing material from a breast.

The Examiner states that "the operation of the [Fox] device to obtain the tissue sample would not change regardless of the location of the tissue sample."

The Fox device includes a tip having an open distal end structured to be braced against a bone surface without penetrating the bone surface, and a rotational element that extends beyond the tip and into the bone to collect a bone sample. As emphasized throughout Fox, the operation of the Fox

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device to obtain a bone sample requires that the tip of the device be braced against the bone, without penetrating into a bone. For example, at column 11, lines 16 through 20, Fox expressly states: "The tip (10, 100, 103) contacts a cutting surface without penetrating into it, and serves as a cutting tool (100) guide or brace or bearing..." [emphasis added].

Fox's teachings are limited to removal of material from a bone, which has a solid, hard surface upon which the instrument tip can be braced. The open distal tip of the Fox device is used without penetrating into the bone. A breast does not include a solid, hard surface that could stand up to such an operation without the patient being seriously injured. Fox's limited teachings, directed to removal of bone cuttings, cannot reasonably be extended to encompass an operation for removal of breast tissue.

The only operation of the Fox device disclosed by Fox is to use the open, distal tip as a brace or guide without penetrating the cutting surface. The Examiner states that "the operation of the [Fox] device to obtain the tissue sample would not change regardless of the location of the tissue sample." Thus, the Examiner's position is that if the Fox device was to be used to remove material from a breast, the open distal tip would not penetrate the breast.

If tissue were to be removed from a breast using the operation disclosed by Fox for removing material from a hard bone, the tip of the device would be required to be braced against or bear against the soft outer surface of the breast while the rotating element passes beyond the tip that is so braced and cuts into the breast. Common sense leads to an appreciation that this hard bone operation taught by Fox is not

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a methodology that would be functional to remove breast tissue. Such an operation, using a bracing, bearing tip of an instrument during the cutting operation as required by Fox, would result in serious injury and even maiming and/or mutilation of the soft skin and other superficial tissues of the breast. Clearly, Fox does not even suggest using the Fox device, operated in the same way as used to obtain a tissue sample from within a hard bone (as stated by the Examiner), to remove tissue from a breast, as argued by the Examiner.

Moreover, even if the Fox device, with the non-penetrating open distal tip, was to be used to remove material from a breast (a use of the Fox device not even remotely suggested by Fox), such use would be in direct contrast to the presently claimed methods. Specifically, the present claims recite that the cannula having an open, distal tip is placed into the breast. The open distal tip of the Fox device does not penetrate the structure to be cut.

Rather than making obvious the present methods, applicant submits that Fox clearly, directly and expressly teaches away from the present claims.

Fox's teachings are so specific and limited to removal of material from hard structures that one of ordinary skill in the art is provided with no motivation from Fox to extend these very limited teachings to encompass an operation for removing material from a soft breast.

Fox does not disclose, teach or even suggest any method for removing material from a breast, let alone a method for removing tissue comprising placing into a breast a cannula having an open distal tip, as recited in the present claims.

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In view of the above, applicant submits that the present claims, and in particular claims 30-33 and 36-45, are unobvious from and patentable over Fox under 35 U.S.C. 103(a).

Applicant further submits that Shiber does not supply the deficiencies apparent in Fox and, therefore, the combination of Fox in view of Shiber does not render the present claims unpatentable.

The Examiner states that Shiber discloses an atherectomy system and method which discloses a cannula having an outer diameter no larger than about 5mm and a cannula no larger than about 2mm, and that "[i]t would be obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Fox to include a cannula diameter of no more than 5mm or 2mm, as per the teachings of Shiber, since it would provide a less invasive medical device for obtaining a tissue sample". Applicant respectfully disagrees.

As explained hereinabove, Fox provides a device with an open distal tip is braced against a bone surface, and a rotating element which channels into the bone while the tip does not penetrate the bone.

Shiber discloses an atherectomy catheter "useful for treating small arteries in the heart or brain... which requires a ...catheter having a diameter as small as 1 mm" (Shiber, column 7, lines 11-15).

Neither Fox nor Shiber even remotely suggests anything regarding removing tissue from a breast, let alone by the methods recited in the present claims.

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In view of the fact that Fox teaches only using an instrument in which an open, distal tip is braced against and does not penetrate a hard surface, there is no motivation or incentive for a person of ordinary skill in the art to combine Fox with the atherectomy-related teachings of Shiber for any purpose, let alone for the purpose of making obvious methods of removing material from the breast of a human or animal in which an open distal end of a cannula is placed into a breast, as recited in the present claims.

Applicant submits that the substantial, even dramatic, differences between a bone and a blood vessel are such that one of ordinary skill in the art would not even attempt to combine the blood vessel-related teachings of Shiber and the deficient bone-related teachings of Fox for any purpose. Moreover, one of ordinary skill in the art would not even attempt to combine the blood vessel-related teachings of Shiber with the bone-related teachings of Fox for the purpose of providing the methods for removing material from a breast as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 34 and 35, are unobvious from and patentable over Fox in view of Shiber under 35 U.S.C. 103(a).

Further, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art, taken singly or in any combination, discloses, teaches or even suggests the presently claimed methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the

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present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are not anticipated by Fox under 35 U.S.C. 102(e), and are unobvious from and patentable over Fox in view of Shiber under 35 U.S.C. 103(a). Therefore, applicant submits that the present claims, that is claims 30-45, are allowable and respectfully requests the Examiner to pass the above-identified application to issuance at an early date.

Should any matters remain unresolved, applicant respectfully requests the Examiner to contact applicant's attorney at the telephone number given below.

Respectfully submitted,



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